



PATENT

J6699(C)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aronson et al.
Serial No.: 09/859,862
Filed: May 17, 2001
For: WET-SKIN TREATMENT COMPOSITONS

Group: 1617
Examiner: Gina C. Yu
Edgewater, NJ 07020
May 27, 2004

DECLARATION OF MICHAEL P. ARONSON FILED UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I Michael P. Aronson, residing at 2 Mandarin Lane, West Nyack, New York, 10994, and a citizen of the United States do hereby declare that:

1. I am the Michael P. Aronson who is one of the named inventors of the above-identified application.

2. I received a Bachelor of Science in Chemistry from the City College of New York in 1968 and the degrees of Master of Science and Doctor of Philosophy in Chemistry from Lehigh University in 1970 and 1973 respectively.
3. During my period of employment with Unilever I have undertaken studies in various technical areas related to the formulation and processing of household and personal care consumer products. I am a named inventor of some 55 United States patents and a named author of some 50 scientific publications.
4. I have read and am familiar with the Office Action which was mailed in connection with the above-identified application on May 20, 2004 including references cited therein.
5. At page 2 of the Office Action, the Examiner rejects the claims over U.S. Patent No. 6,080,708 to Glenn Jr. et al. Specifically, the Examiner states that the compositions of Glenn Jr. contains, among other components, as stabilizer trihydroxystearin or silica, which are termed a structurant by applicants.

The Examiner view expressed on pages 3-4 is that these stabilizers, which are used to stabilize the aqueous phase are not necessarily homogenized in the aqueous phase. Examiner further asserts that hydroxystearin is an oily compound and that Glenn teaches using oil thickeners for the lipid phase (column 9, lines 21-24).

6. During the week of May 17, 2004, I have reviewed U.S. Patent 6,080,708 to Glenn, Jr. et al. and compared it with the invention described by Aronson et al in SN 09/859,862. I also reviewed additional experiments carried out by Dr. Liang Tsaur of Unilever's Edgewater, NJ Laboratory and other pertinent technical information in Unilever's files. The Examiner's attention is drawn to the following pertinent conclusions drawn from this review.

7. Glenn Jr. teaches an aqueous phase of oil-in-water emulsions that "comprises a crystalline hydroxy-containing stabilizer, a surfactant and water..." (column 4, lines 20-23 emphasis added). Glenn Jr. clearly states that this stabilizer is a component of the aqueous phase. (column 4, lines 18-31). That these stabilizers are taught as water-phase structurants is further evidenced by the description of the "SINGLE VESSEL PROCESS" used to prepare the compositions at column 17, lines 26-65:

"1. Trihydroxystearin is added to distilled water and allowed to mix until fully hydrated...."

"8. A premix of lipid blend is added to the mixture..."

Thus, the oil phase is added only after the trihydroxystearin is dispersed in water to form the network in the aqueous phase.

8. Glenn Jr. also contemplates that "The use of oil thickening polymerscan also be included in the water phase." That is, Glenn Jr. teaches using oil thickening polymers in the aqueous phase of the emulsion and not to structure the oil phase.
9. By contrast, applicants' claims recite compositions in which the oil phase is structured with solid particles that form a stable 3-dimensional network within the oil phase. The process used to prepare the compositions as exemplified in Example 1 (page 39, lines 16-27) of applicants' specification and described in pertinent part below is distinctly different from the process disclosed by Glenn Jr.

"Samples were prepared using the method described as follow.
An oil premix containing all the emollient oils in the formulation (sunflower seed oil, Parsol MCX, petrolatum, polybutene or trihydroxystearin) is prepared by mixing the oils at 70 to 85°C to

form a clear uniform mixture. The oil mixture is then cooled below 40°C to form a viscous oil mixture before adding into the formulation. In a separate mixer, a thickened aqueous solution containing water soluble polymer (Xanthan Gum or Carbopol), surfactants, glycerin, perfume and Glydant plus with a pH in the range of 6.5 to 7.0 was prepared. 15 parts of the oil premix was then injected into 85 parts of the thickened aqueous solution using a syringe. The aqueous solution containing lumps of oil mixture was then passed through a screen to make the final product containing large oil droplets with size in the range of 20 to 300 microns."

10. Glenn Jr. further teaches that "The stabilizer is used to form a crystalline stabilizing network in the emulsion that prevents the lipophilic skin moisturizer agent from coalescing and phase splitting in the product." (column 4, lines 32-35).
11. By contrast, applicants have noted on page 11, lines 14-18 of the specification, that: "The dispersed structured oil phases of this invention are also prone to stick together and coalesce. Without being bound by theory, it is believed that the stable solid network facilitates coalescence by providing aspirates that induce film rupture. The same property that is useful in achieving efficient deposition on skin also makes the structured phase prone to instability on storage." (emphasis added). Thus, the location of the oil network, i.e., whether it is in the water or in the oil phase, is far from incidental and has a real and tangible effect on the properties of the emulsion.
12. To demonstrate the differences in emulsion properties that depend upon the phase in which the network of solids is located, Dr. Tsaur prepared two emulsions that contained 9.5% sunflower seed oil, 0.5 % trihydroxystearin, 0.35% Carbopol (ETD2020), 1% alkylpolyglucoside (Plantaren 2000N), 1% Perfume and 0.2 % glydant (similar in composition to Example 1D in applicants'

specification). In one emulsion, trihydroxystearin was dispersed in the oil phase as taught by applicants. In the other emulsion, the trihydroxystearin was dispersed in the water phase according to the teachings of Glenn Jr. (column 17, lines 26-65).

Photomicrographs of these dispersions are compared in the attached Fig. 1. As can be seen, the emulsion droplets prepared according to applicants' specification have a markedly different appearance when viewed under polarized light. The droplets are bright indicating a network of crystals present in the oil phase and they are non-spherical indicating the network has a yield stress. By contrast, the droplets prepared according to Glenn Jr. are clear and spherical indicating the absence of a crystalline network in the oil phase. Thus, the two processes indeed produce very different oil phases.

The two emulsions also behave very differently when diluted as is shown in Fig. 2. The emulsion prepared according to the applicants' specification forms large flocs when diluted 1/10 with water, i.e., the emulsion is not stable as was disclosed in the specification. By contrast, the emulsions prepared according to Glenn Jr. do not flocculate and remain stable. Thus, when the trihydroxystearin is dispersed in the oil phase it does not stabilize the oil-in-water emulsion as required by Glenn Jr.

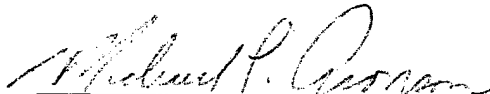
13. As stated by applicants, it is the presence of a network in the oil phase that leads to the high retention of oil on wet skin. I have also reviewed the results of previous measurements carried out at Unilever's Edgewater laboratory on the oil deposition from emulsions whose aqueous phase is structured by trihydroxystearin and whose composition is very similar to and within the scope disclosed by Glenn Jr. The oil retention index by the in-vitro tests disclosed in applicant's specification was found to be in the range of 0.01 to 0.02. The oil retention index as discussed in applicants' specification is the fraction of the total


oil from the composition that remains on the skin after rinsing, i.e. 1-2% of the applied dose in this case.

By contrast, the oil retention index of emulsions in which the oil phase is structured by trihydroxystearin is typically 0.45 and higher (see for example, Aronson et al specification, Page 39, Table 1 - Example 1D). Thus, the efficiency of the composition in retaining oil on the skin after rinsing is a factor of 20 to 40 times higher when the oil phase is structured by trihydroxystearin rather than when the aqueous phase is structured by trihydroxystearin.

14. From the analysis and information cited above I conclude that the emulsion compositions disclosed by Glenn Jr. et al in U.S. Patent 6,080,708 are fundamentally different from those disclosed in applicants' specification. The trihydroxystearin network is intentionally located in different phases, which is governed by the different methods by which the emulsions are prepared. Moreover, this difference leads to distinctly different emulsion properties. Dispersing the particulates in the water phase is critical to Glenn Jr. achieving an emulsion stabilizing effect. In contrast dispersing the particulates in the oil phase to achieve a 3-dimensional network in the oil phase is critical in achieving the emulsion destabilizing effect which is believed responsible for the much higher oil retention on wet skin exhibited by the compositions disclosed by Aronson et al.

15. I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.


Michael P. Aronson, Ph.D.

Dated: May 27, 2004


O.I.P.E. 57
FEB 03 2005
BATES

Fig 1. Photomicrographs of Emulsion Droplets

Prepared according to present application

Prepared according to Glenn Jr et al - US 6080708

Non-polarized
light

x-polarized
light

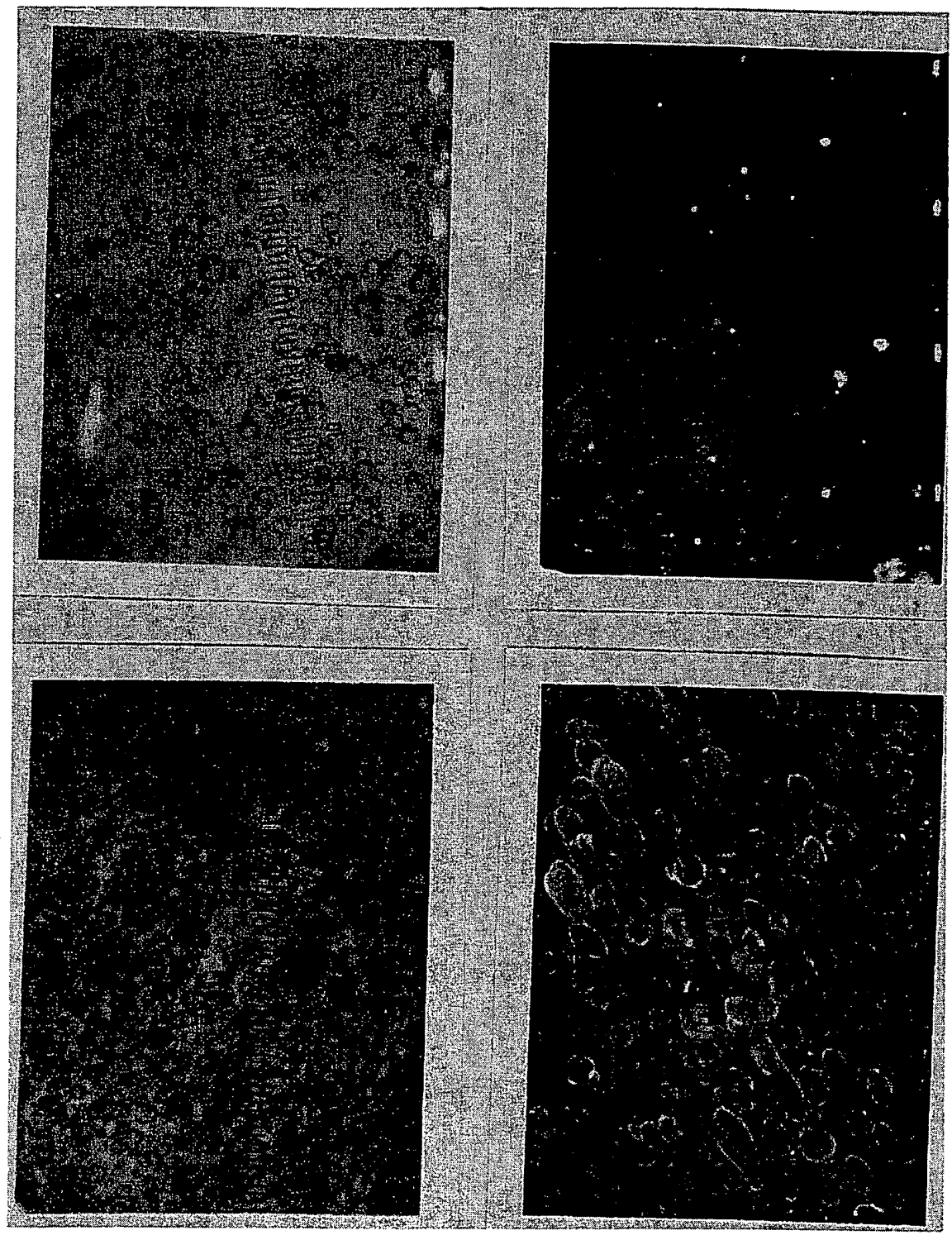
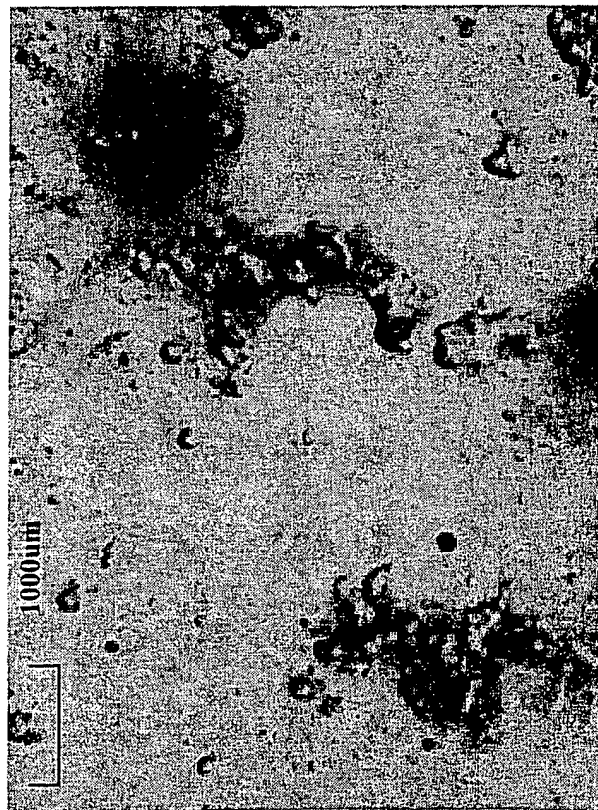




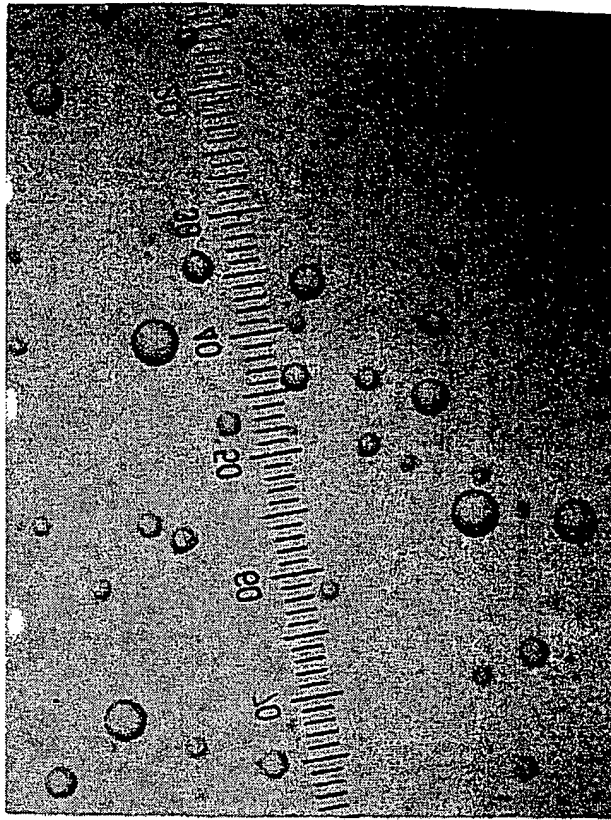
Fig 2. Photomicrographs of Emulsion Droplets of diluted emulsions (1/10)

Note differences flocculation (stability)

Prepared according to present application



Prepared according to Glenn Jr et al - US 6080708



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